Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Ofloxacin Teva 200 mg

Tablets

Composition:
Each tablet contains:
Ofloxacin 200 mg

For information about inactive ingredients and allergens in the medicine, see section 2 – 'Important information about some of this medicine's ingredients' and section 6 – 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is intended for treatment of bacterial infections caused by bacteria susceptible to ofloxacin: respiratory tract infections, pneumonia, ear, nose or throat infections, infections of the kidneys, urinary tract and genital organs (including gonorrhea, a sexually transmitted disease), gastrointestinal infections including bacterial enteritis, soft tissue and skin infections, bone and joint infections.

Therapeutic group:
Antibiotic medicine belonging to the fluoroquinolone group.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6 – 'Additional information').
- You have previously had an allergic reaction to a quinolone antibiotic. If you have had an allergic reaction to any antibiotic in the past, consult your doctor before taking Ofloxacin Teva.
- You have had inflammation of the tendons (tendinitis) after taking fluoroquinolone antibiotics in the past.
- You have epilepsy or have had a seizure or convulsion in the past.
- You suffer from glucose-6-phosphate dehydrogenase deficiency (an inherited disease that affects the red blood cells). Upon treatment with Ofloxacin Teva, the red blood cells may break down, causing anemia or jaundice.
- You are pregnant or breastfeeding.
- You are under the age of 18 years, or if you are over the age of 18 years, but think you are still in the stages of growth.
- You have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Ofloxacin Teva is not suitable for people who have inherited diseases that may cause problems when they take these sugars.
- You suffer from methicillin-resistant staphylococcus aureus (MRSA) infection.
- You suffer from vision disorders.

Special warnings regarding use of this medicine
Heart problems
Caution should be taken when using this medicine if you were born with or have a family history of prolonged QT interval (seen on ECG, recording of the electrical activity of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called bradycardia), have a weak heart (heart failure), have had a heart attack (myocardial infarction) in the past, you are a woman or elderly, or you are taking other medicines causing abnormal ECG changes (see section 2 'Interactions with other medicines').

Before treatment with Ofloxacin Teva 200 mg, tell your doctor if:

- You suffer or have suffered from a mental illness in the past.
- You have liver or kidney problems. Make sure you tell the doctor about any liver or kidney problem before you start taking Ofloxacin Teva, because the dose may need to be lowered.
- You have an illness of the nervous system called myasthenia gravis, in which the muscles are weak and tire easily.
- You are elderly or have been prescribed corticosteroids (used to treat asthma and other chronic lung diseases), as they may increase the risk of swelling and pain in the tendons.
- You have diabetes.
- You are taking a medicine called fenbufen or other medicines of the NSAIDs group, vitamin K antagonists.
- You are taking theophylline.
- You have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- You have been diagnosed with leaking heart valves (heart valve regurgitation).
- You have a family history of aortic aneurysm, aortic dissection, congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, vascular Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease] or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis and rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).

Before taking this medicine
You should not take antibiotic medicines of the fluoroquinolone/quinolone group, including Ofloxacin Teva, if you have experienced any serious adverse reaction in the past while using quinolones or fluoroquinolones. In such case, inform your doctor as soon as possible.

- If you feel sudden, severe pain in your abdomen, chest or back, which may be symptoms of aortic aneurysm or dissection, go immediately to an emergency room. Your risk is increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat, or if you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

During treatment with Ofloxacin Teva

- You may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock). Even after taking the first dose, there is a chance that you may experience a severe, sudden allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, nausea or faintness, or experience dizziness upon standing. If this happens, stop taking Ofloxacin Teva and contact your doctor immediately.
- **Prolonged, disabling and potentially irreversible serious side effects:**
  Fluoroquinolone/quinolone antibacterial medicines, including Ofloxacin Teva, have been associated with rare but serious side effects, some of them being long lasting (continuing for months or years), disabling or potentially irreversible. These side effects include tendon, muscle, and joint pain in the upper and lower limbs; difficulty in walking; abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paresthesia); sensory disorders including impairment of vision, taste, smell, and hearing; mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion or depression; memory impairment; severe fatigue and severe sleep problems. No medicines have been found to be effective treatment for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.
  If you experience any of these side effects after taking Ofloxacin Teva, do not take any more doses and contact your doctor immediately. You and your doctor will decide whether to continue treatment, considering alternative options.
- You may experience psychiatric reactions when taking Ofloxacin Teva, including when taking it for the first time. If you suffer from depression or psychosis, your symptoms may become worse when taking Ofloxacin Teva. In rare cases, depression and psychosis can progress to thoughts of suicide or suicide attempts. If this happens, stop taking Ofloxacin Teva and contact your doctor immediately. You may not notice certain changes in your mood and behavior, so it is very important to tell your friends and family that you are taking Ofloxacin Teva and that there may be rare psychiatric side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about.
- You may experience symptoms of liver problems such as loss of appetite, yellowing of the skin and whites of the eyes, dark urine, itching or abdominal tenderness. Stop taking Ofloxacin Teva immediately.
- Diarrhea may develop during treatment with antibiotics, including Ofloxacin Teva, or several weeks after you have stopped treatment with them. If the diarrhea becomes severe or persistent, or if you notice that your stool contains blood or mucus, tell your doctor immediately. Ofloxacin Teva treatment must be stopped immediately, as this may be life-threatening.

Pain and swelling of the joints and tendon inflammation or rupture may rarely occur. Your risk is increased if you are elderly (above the age of 60 years), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Tendon inflammation and ruptures may occur during the first 48 hours after starting the treatment and even several months after discontinuing treatment with Ofloxacin Teva. With the onset of the first sign of tendon pain or inflammation (for example, in the ankle, wrist, shoulder or knee), stop taking Ofloxacin Teva, contact your doctor and let the painful area rest. Refrain from unnecessary physical activity, since it may increase the risk of tendon rupture.

- You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning sensation, tingling, numbness and/or weakness, especially in the feet and legs or hands and arms. If this happens, stop taking Ofloxacin Teva and inform your doctor immediately to prevent the development of potentially irreversible medical condition.
- Tell your doctor if you or a member of your family is known to have a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD), since you may experience a risk of anemia when using ofloxacin.
- Do not expose yourself to long periods of strong sunlight while taking the tablets. Use a sun protection cream if you cannot avoid strong sunlight.
- Do not use a light therapy lamp (sun-lamp) or solarium.
- You may be more susceptible to infection with other bacteria.
- Inform the doctor that you are taking Ofloxacin Teva if you are supposed to undergo any medical tests, as the medicine may affect the results.
- You may experience skin reaction problems such as Stevens-Johnson syndrome, a rare, serious disorder of the skin and mucous membrane, or toxic necrolysis of the upper skin layer, a condition involving detachment of this layer from the lower skin layers.

Quinolone antibiotics may cause an increase in blood sugar levels above the normal levels (hyperglycemia), or a decrease in blood sugar levels below the normal levels. In severe cases, this condition may lead to loss of consciousness (hypoglycemic coma) (see section 4 – 'Side effects'). This is important for people who have diabetes. If you suffer from diabetes, your blood sugar should be carefully monitored.

Children and adolescents:
Ofloxacin Teva should not be given to children or growing adolescents.

Tests and follow-up

- The doctor may want you to perform blood tests for follow-up if you are taking Ofloxacin Teva for more than 2 weeks.

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Especially if you are taking:

- Anticoagulants (tablets preventing blood clotting e.g. warfarin), as bleeding time may be longer.
- Antacids, sucralfate, didanosine, aluminum, iron, magnesium or zinc preparations (see section 3 - 'How to use this medicine').
- Medicines for control of blood sugar levels (e.g. glibenclamide), as the concentrations of these medicines in the blood may increase and they may have a greater effect.
- Theophylline or non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, diclofenac or fenbufen, as some people have fits when taking these medicines with ofloxacin.
- Medicines that may affect your kidney function (e.g. cimetidine, furosemide, probenecid or methotrexate), as these medicines may sometimes increase the blood levels of ofloxacin.

You must tell your doctor if you are taking other medicines that may alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, procainamide), tricyclic antidepressants e.g. amitriptyline, clomipramine, certain antibiotics (belonging to the group of macrolides, e.g. erythromycin or azithromycin), some antipsychotics (e.g. olanzapine, quetiapine).

Pregnancy, breastfeeding, and fertility
Do not use Ofloxacin Teva if you are pregnant or breastfeeding.
There is limited information regarding the use of ofloxacin in pregnant women.
Ofloxacin is known to be excreted in breast milk in small quantities.

Driving and using machines
Ofloxacin Teva may make you feel sleepy, dizzy or may affect your eyesight, which may affect your ability to concentrate. If you are affected, do not drive or operate machines.

Important information about some of this medicine's ingredients
Patients who are intolerant to **lactose** should note that Ofloxacin Teva tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 23 mg sodium per tablet, that is to say essentially "sodium free".

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

Do not take this medicine more than 8 weeks continuously.

Patients with liver disease and patients with impaired renal function will have their dosage adjusted by the doctor depending on their condition.

Do not exceed the recommended dose.

Taking the medicine
Swallow the tablets whole with a full glass of water.
Do not chew or crush the tablets.
The tablet may be split at the score line into 2 equal doses.

Taking Ofloxacin Teva in combination with antacids, sucralfate, aluminum, iron, magnesium or zinc preparations:
Wait at least 2 hours between the intake of Ofloxacin Teva and the intake of any of the above medicines; otherwise, Ofloxacin Teva may not work properly.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room.
Overdose may cause dizziness, confusion, fits, loss of consciousness, QT interval prolongation, feeling the presence of an object when no object is present, involuntary shaking of the body or limbs, nausea and severe stomach problems.

Please bring this leaflet, any remaining tablets and the medicine package with you to the hospital or doctor so that they know which tablets were consumed.

If you forgot to take the medicine
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next tablet. Do not take a double dose to compensate for the forgotten dose.

Follow the treatment as recommended by your doctor.

If you stop taking this medicine
Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor. If you fail to do so, the symptoms may return.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Ofloxacin Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

If the following side effects occur, stop taking Ofloxacin Teva and immediately contact your doctor or go to the hospital:

- An allergic reaction, sometimes even after taking your first dose, which may include swelling of the lips, face or neck leading to severe difficulty breathing, skin rash or hives, fast heart rate, low blood pressure, fever, burning of the eyes, throat irritation, coughing, wheezing, shock or blood disorders.
- Skin problems that come from an allergic reaction or infection (drug eruption), visible accumulation of fluid within or beneath the skin (vesiculobullous rash), skin rash caused by sunlight (photosensitivity reaction), inflammatory skin eruption (erythema multiforme).
- Inflammation and ulceration of the mouth, eyes, gut and genitals. These may be due to Stevens-Johnson syndrome or toxic epidermal necrolysis, which are serious illnesses.
- Tendon discomfort, including inflammation and rupture, particularly if you are elderly or also taking corticosteroids e.g. prednisolone.
- Fits, agitation, nightmares, anxiety, depression, hallucinations, feeling of wanting to harm yourself or other disturbances of the mind, confusion, ringing in the ears, unsteadiness, shaking, disturbances of sensation, numbness, sensation of "pins-and-needles", blurred, double or odd color vision, problems with or loss of hearing, taste or smell.
- Diarrhea containing blood.
- Inflammation of the liver, which may be severe. Loss of appetite, yellowing of the skin and eyes, dark-colored urine, irritation or tenderness in the abdomen. All these may be signs of liver problems which may include fatal liver failure.

The following side effects have been reported at the relative frequencies described below:
Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Fungal infections, resistance to pathogens.
- Headache, dizziness, sleep disturbances and restlessness.
- Eye irritation, sensation of spinning (vertigo), cough, nose inflammation.
- Nausea or vomiting, diarrhea, abdominal pain.
- Skin rash, itching.

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Cases of long lasting (up to months or years) or permanent side effects have been associated with quinolone and fluoroquinolone antibiotics. These side effects may include tendon inflammation, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as "pins and needles", tingling, tickling, burning sensation, numbness or pain (neuropathy), fatigue, sleep disorders, memory impairment, mental health effects which may include, but are not necessarily limited to, anxiety, panic attacks, confusion, or depression, as well as impairment of hearing, vision, and taste and smell. No medicines have been found to be effective treatment for the symptoms of long lasting or disabling side effects associated with fluoroquinolones.
- Loss of appetite.
- Sleepiness.
- Faster heart rate (tachycardia).
- Low blood pressure.
- Difficulty breathing or wheezing, shortness of breath.
- Bowel inflammation which may cause bleeding.
- Liver function impairment with abnormal blood test results.
- Urticaria (hives).
- Menstrual disturbances (such as hot flushes), excessive sweating, pustular rash.
- Increased creatinine levels in the blood.
- Delirium (acute confusional state).

Very rare side effects – effects that occur in less than 1 in 10,000 users:

- Anemia (reduction in the number of red blood cells causing pale or yellow skin, unusual tiredness or weakness).
- Other blood disorders when the numbers of different types of cells in the blood may fall. Symptoms can include fever, chills, sore throat, ulcers in the mouth and throat, unusual bleeding or unexplained bruising.
- Abnormal dreams or mental illnesses.
- Impairments of voluntary movements i.e. tremor, tics. Changes in muscle tone, slowness of movement.
- An allergic reaction in the eye or on the skin around the eye.
- Failure of blood circulation in the body.
- Flushing.
- Bruises similar to rash.
- Inflammation of blood vessels, often with skin rash.
- Muscle weakness, joint and muscle pain.
- Effects on kidney function, which may lead to kidney failure.
- Unbalanced walk.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Severe reduction in the number of white blood cells, which makes infections more likely.
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycemic coma). See section 2.
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, recording of the electrical activity of the heart).
- Inflammation of the lungs which causes breathlessness, cough and raised temperature (allergic pneumonitis).
- Severe shortness of breath.
- Acute generalized exanthematous pustulosis (red swollen area with numerous small pustules).
- Pain or muscle weakness, abnormal muscle breakdown which may lead to kidney problems.
- Muscle tear (partial or full).
- Inflammation of the kidneys which may cause swollen ankles or high blood pressure.
- Ofloxacin may trigger an attack of porphyria in susceptible patients.
- Increase in blood sugar levels (especially in diabetics).
- Nervousness.
- Involuntary shaking of the body or uncontrollable movement of the upper body or lower extremities.
- Loss of taste function of the tongue.
- Temporary loss of consciousness caused by a fall in blood pressure.
- Fever.
- Painful, difficult, or disturbed digestion, which may be accompanied by symptoms such as nausea and vomiting, heartburn, bloating and abdominal discomfort, accumulation of gas in the gastrointestinal system, painful defecation, inflammation of the pancreas.
- Inflammation of the mouth and lips.
- Inflammation and stiffness of the joints.
- Loss or lack of bodily strength including pain in the back, chest and extremities.
- Bone marrow failure, which may lead to pancytopenia (a medical condition in which there is a reduction in the number of red and white blood cells, as well as platelets).
- Inflammation of the eye (uveitis).
- Extensive skin redness (exfoliative dermatitis).

Cases of an enlargement or weakening of the aortic wall or a partial tear in the aortic wall (aneurysm or dissection), which may lead to complete rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See section 2.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! This and all other medicines should be kept in a closed place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store in a dry place, below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, pregelatinized starch, hypromellose, croscarmellose sodium, magnesium stearate, colloidal anhydrous silica, titanium dioxide, macrogol, triacetin.

What the medicine looks like and contents of the package:
White, round, film coated tablets, breakline on both sides. One side of the tablet debossed "FXN" on one side of the breakline and "200" on the other side.

Package sizes: 10 or 20 tablets.
Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 121.98.30147

DOR-Ofl-200mg-PIL-0324-12

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